DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 26, 2014

Genesis Fracture Care, Incorporated
% Ms. Christine Scifert
Memphis Regulatory Consulting, LLC
3416 Roxee Run Cove
Bartlett, Tennessee 38133

Re: K142938
Trade/Device Name: G3™ Active Plate® Large Fragment System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: October 8, 2014
Received: October 9, 2014

Dear Ms. Scifert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K142938

Device Name

G3™ Active Plate® Large Fragment System

Indications for Use *(Describe)*

The system is intended for use in adult and pediatric cases (subpopulation: transitional adolescent B (18 years to <21 years) requiring stabilizations of mal-unions, non-unions, and osteotomies of long bones, as well as repair of closed and open fractures. The system is indicated for the fixation of long bone fractures including but not limited to fractures of the humerus, tibia, and femur, particularly in osteopenic bone.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

G3™ Active Plate® Large Fragment System

November 21, 2014

Company: Genesis Fracture Care, Inc.
13568 SE 97th Ave
Suite 202
Clackamas, OR 97015
503-528-4048
503-413-5216 (fax)

Primary Contact: Christine Scifert

Company Contact: Michael Bottlang

Trade Name: G3™ Active Plate® Large Fragment System

Common Name: Plate, Fixation, Bone
Screw, Fixation, Bone

Classification: II

Regulation Number: 888.3030 - Single/multiple component metallic bone fixation appliances and accessories
888.3040 - Smooth or threaded metallic bone fixation fastener

Panel: 87-Orthopedic

Product Code(s): HRS, HWC

Device Description: The G3™ Active Plate® Large Fragment System is a straight plate and locking screw system comprised of a variety of sizes to accommodate various patient anatomy and pathology. The plates and screws are intended to be used for long bone fracture fixation. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI) and silicone elastomer in the subject device. The screws are 5.0 mm diameter and come in lengths ranging from 14 to 145 mm. The plates range in size from 6 holes to 14 holes. The plates incorporate sliding elements, which are constrained within the plate and embedded in a silicone elastomer sheath that is bonded to both the plate and

sliding element. Once locking screws are inserted, the active elements allow for independent controlled axial translation of the screws. All instruments are made from stainless steel.

Indications for Use: The system is intended for use in adult and pediatric (subpopulation: transitional adolescent B (18 years to <21 years) cases requiring stabilizations of mal-unions, non-unions, and osteotomies of long bones, as well as repair of closed and open fractures. The system is indicated for the fixation of long bone fractures including but not limited to fractures of the humerus, tibia, and femur, particularly in osteopenic bone.

Substantial Equivalence: The subject components were demonstrated to be substantially equivalent to the following plate and screw systems previously cleared by the FDA:

- Synthes 4.5mm LCP Reconstruction Plates (K051986, S.E. 09/08/2005)
- Smith & Nephew PERI-LOC Bone Plating and Screw System (K033669, S.E. 12/10/2003 and K083032, S.E. 01/07/2009)
- Zimmer MotionLoc™ Screws for NCB® Locking Plate system (K042695; S.E.10/29/2004 and K101696; S.E. 09/10/2010)
- Zimmer Periarticular Locking Plate System (K040593; S.E. 04/12/2004)

Additionally, Medisil Silicone Sheeting (K040042; S.E. 4/1/2004) was provided as a reference device for the silicone elastomer.

In addition to being substantially equivalent in terms of intended use, material, and geometry, the subject G3™ Active Plate® Large Fragment System has also demonstrated to be substantially equivalent in terms of construct stiffness performance when compared to the previously cleared Zimmer MotionLoc™ Screws for NCB® Locking Plate System (K042695; S.E.10/29/2004) with (K101696; S.E. 09/10/2010). The subject G3™ Locking Screws have also demonstrated to be substantially equivalent to those in the previously cleared Zimmer Periarticular Locking Plate System (K040593; S.E. 04/12/2004) in terms of performance. Finally, the G3™ Active Plate® Large Fragment System has demonstrated to be substantially equivalent to the Synthes LCP Plate (K05186; S.E. 9/8/2005) in construct fatigue testing.

	Subject of Present 510(k): **G3™ Active Plate™**	**Predicate Devices**
Intended Use/ Indications for Use	The G3™ Active Plate® Large Fragment System is intended for use in adult and	Inclusive

	pediatric cases requiring stabilizations od mal-unions, non-unions, and osteotomies of long bones, as well as repair of closed and open fractures, The system is indicated for the fixation of long bone fractures including, but not limited to, fractures of the humerus, tibia, and femur, particularly in osteopenic bone.	
Primary Material	Titanium	Titanium or Stainless Steel
Geometry and Dimensions	Plates: 6 - 14 holes; Lengths: 145 mm - 305 mm Locking Screws: Diameter: 5.0 mm Lengths: 14 mm - 145 mm	Plates: 2 - 24 holes; Lengths: 56 mm - 444 mm Locking Screws: Diameter: 4.0mm – 6.5 mm Lengths: 10 mm - 130 mm
Active feature (if applicable)	Sliding elements	Flexible screw (K101696)

Performance Testing: Biocompatibility of the G3™ Active Plate® Large Fragment System was evaluated per ISO 10993-1. Mechanical testing, including stiffness, fatigue, pullout, torsion, torque, construct fatigue and wear have been performed per ASTM F543 and ASTM F382 on the subject G3™ Active Plate® Large Fragment System, as well as the G3™ locking screws used within the system and the results have shown them to be substantially equivalent to the predicate plate and screw systems.